REMARKS

Claim 76 is pending in the instant application and is currently subject to enablement and written description rejections under 35 U.S.C § 112, first paragraph. Applicants respectfully request that the following remarks be made part of the record in the file history of the instant application.

THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH FOR ENABLEMENT SHOULD BE WITHDRAWN

Claim 76 stands rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. Specifically, the Office Action indicates that the specification of the current application is only enabling for a container containing perforations, and therefore would not enable one of ordinary skill in the art to practice a method commensurate in scope with claim 76. In particular, the Office Action relies on the specification, page 4, lines 12-15, for a recitation of what it identifies as the broadest interpretation of the container.

THE LEGAL STANDARD

The test for enablement is whether one reasonably skilled in the art could make or use the invention, without undue experimentation, from the disclosure in the patent specification coupled with information known in the art at the time the patent application was filed. *U.S. v. Telectronics Inc.*, 857 F.2d 778, 8 USPQ2d 1217 (Fed. Cir. 1988). In fact, well known subject matter is preferably omitted. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) ("a patent need not teach, and preferably omits, what is well known in the art."). Further, one skilled in the art is presumed to use the information available to him in attempting to make or use the claimed invention. See *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941 (Fed. Cir. 1990) ("A decision on the issue of enablement requires determination of whether a person skilled in the pertinent art, using the knowledge available to such a person and the disclosure in the patent document, could make and use the invention without undue experimentation."). These enablement rules preclude the need for the patent

applicant to "set forth every minute detail regarding the invention." *Phillips Petroleum Co. v. United States Steel Corp.*, 673 F. Supp. 1278, 1291 (D. Del. 1991); see also *DeGeorge v. Bernier*, 768 F.2d 1318, 1323 (Fed. Cir. 1985).

Undue experimentation is experimentation that would require a level of ingenuity beyond what is expected from one of ordinary skill in the field. *Fields v. Conover*, 170 USPQ 276, 279 (CCPA 1971). The factors that can be considered in determining whether an amount of experimentation is undue have been listed in *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Among these factors are: the amount of effort involved, the guidance provided by the specification, the presence of working examples, the amount of pertinent literature and the level of skill in the art. The test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, so long as it is merely routine. *Id.*

Further, while the predictability of the art can be considered in determining whether an amount of experimentation is undue, mere unpredictability of the result of an experiment is not a consideration. Indeed, the Court of Custom and Patent Appeals has specifically cautioned that the unpredictability of the result of an experiment is not a basis to conclude that the amount of experimentation is undue in *In re Angstadt*, 190 USPQ 214 (CCPA 1976), at 218-219:

> [If to fulfill the requirements of 112, first paragraph, an applicant's] disclosure must provide guidance which will enable one skilled in the art to determine, with reasonable certainty before performing the reaction whether the claimed product will be obtained, ... then all "experimentation" is "undue" since the term "experimentation" implies that the success of the particular activity is uncertain. Such a proposition is contrary to the basic policy of the Patent Act. *Id.* at 219.

Thus, all that is required is a reasonable amount of guidance with respect to the direction of the experimentation; reasonable certainty with regard to the outcome of the experimentation is not required.

In addition, the Patent and Trademark Office bears the initial burden of establishing a *prima facie* case of non-enablement. *In re Marzocchi*, 169 USPQ 367, 369 (C.C.P.A. 1971); M.P.E.P. § 2164.02. A patent applicant's specification which contains a teaching of how to make and use the invention must be taken as enabling unless there is reason to doubt the objective truth of the teachings which must be relied on for enabling support. *Id.*

The Claimed Device Meets the Enablement Requirement

The specification clearly enables one of ordinary skill in the art to make or use containers, other than perforated, for the device used in the method of the current invention. The device provides an artificial environment that mimics the composition and role of a lymph node. *See* page 12, lines 1-6. The device accomplishes this by providing for a matrix that contains antigen and a diffusion barrier limiting the passive diffusion of antigen, cytokines, or immune factors from the device but permitting the active ingress and egress of immune cells from the device. *See* page 19, lines 12-18. The present application discloses a preferred embodiment of the device wherein a porous matrix acts as a reservoir for the antigen and other molecules and a perforated but otherwise impermeable container is used to generate the diffusion barrier. In the context of the preferred embodiment, the specification acknowledges that one of ordinary skill in the art would recognize other means of readily accomplishing the principle of the novel device. *See e.g.,* Page 19, line 12-Page 23, line 7.

Regarding the container, the specification clearly discloses the materials and methods of manufacturing the containers of the present invention. *See* page 21, line 8-page 22, line 16. Further the specification indicates that the container should have a means for limiting the passive diffusion of molecules out of said device without limiting the active movement of immune cells into or out of said device. Such means are disclosed at page 22, line 17 to page 23, line 4. The specification further indicates that "a skilled artisan will be aware of other parameters which will achieve the same objectives as set forth above, that is, to provide unrestricted cellular ingress and egress but to restrict and confine the diffusion of small molecules, such as cytokines, within the device." *See* page 22, lines 4-7. As an example of an alternative to a perforated container, the specification at page 19, line 22, and at page 23, lines 4-5, indicates that a device utilizing tubing as the container may have the ends of the tubing left opened to act as perforations, without perforating the container itself. Thus, the current specification provides sufficient disclosure to enable one of ordinary skill in the art to make and use a container, other than a perforated container, in accordance with the current invention.

Further, Example 13 of the present application provides an assay with which to determine whether the device, specifically the container, maintains the diffusion barrier critical to the devices

enhanced immunization function. *See* page 38, line 4.

Thus, the specification provides sufficient disclosure to enable one of ordinary skill in the art to make and use a container of the scope claimed in claim 76. In view of these remarks, Applicants respectfully submit that the rejection of claim 76 under 35 U.S.C. § 112, first paragraph, should be withdrawn.

THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, FOR WRITTEN DESCRIPTION SHOULD BE WITHDRAWN

Claim 76 stands rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. Specifically, the Office Action alleges that the phrase "means for limiting the passive diffusion of molecules out of said device without limiting the active movement of immune cells into or out of said device" is not present in the specification of the current application, and therefore the specification does not reasonably convey to one skilled in the art that the inventor(s) had possession of the claimed invention.

THE LEGAL STANDARD

The test for sufficiency of written description is whether the disclosure of the application 'reasonably conveys to the artisan that the inventor had possession' of the claimed subject matter. *In re Kaslow*, 707 F.2d 1366, 1375, 217 U.S.P.Q. (BNA) 1089, 1096 (Fed. Cir. 1983); accord *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563; *see also*, *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575, 227 U.S.P.Q. (BNA) 177, 179 (Fed. Cir. 1985). The Court of Appeals for the Federal Circuit has repeatedly considered the written description requirement and consistently found that exacting detail is not necessary to meet the requirement:

> If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if [not] every nuance of the claims is explicitly described in the specification, the adequate written description requirement is met. *In re Alton*, 76 F.3d 1168, 37 USPQ2d 1578 (Fed. Cir. 1996).

The criteria for determining sufficiency of written description set forth in Guidelines for

Examination of Patent Applications Under the 35 U.S.C. 112 ¶ 1, "Written Description Requirement" ("the Guidelines") (published in the January 5, 2001 Federal Register at Volume 66, Number 4, p. 1099-1111), specifies that:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see (1)(a) above), reduction to drawings (see (1) (b) above), or by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see (1)(c), above). *Id.* at p. 1106, column 3, *l.* 13-29.

Where the specification discloses any relevant identifying characteristics, *i.e.*, physical, chemical and/or functional characteristics sufficient to allow a skilled artisan to recognize the applicant was in possession of the claimed invention, a rejection for lack of written description under Section 112, first paragraph, is misplaced. *Id.*

In accordance with the Guidelines, what is conventional or well known to one of skill in the art need not be disclosed in detail (*Id.* at p. 1105, column 3, *ll.* 39-41), and, where the level of knowledge and skill in the art is high, a written description question should not be raised. *Id.* at p. 1106, column 1, *ll.* 34-36. See also *Capon v. Eshhar*, 418 F.3d 1349, at 1357 (Fed. Cir. 2005).

It is well established that the law does not require that the specification provide support in exactly the same words as used in the claims to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. It is enough that the description conveys to one skilled in the art that the applicant had possession of the invention. For example, see *In re Wilder*, 736 F.2d 1516, 1520, 222 U.S.P.Q. 369, 372 (Fed. Cir. 1984):

> It is not necessary that the claimed subject matter be described identically, but the disclosure originally filed must convey to those skilled in the art that applicant has invented the subject matter later claimed.

See also *Application of Lukach*, 442 F.2d 967, 969, 169 U.S.P.Q. 795, 796 (C.C.P.A. 1971): "[T]he invention claimed does not have to be described in *ipsis verbis* in order to satisfy

the description requirement of § 112."

The Claimed Device Meets the Written Description Requirement

Applicants note that the claim limitation "means for limiting the passive diffusion of molecules out of said device without limiting the active movement of immune cells into or out of said device" was included in claim 57 as originally filed in the parent application, U.S. Patent Application No. 09/259,929.

Further, Applicants refer to the specification at page 14, lines 2-7. The specification clearly indicates that the container of the device acts as a diffusion barrier, by maintaining within the device high levels of cytokines and other co-stimulatory factors produced by immune cells in proximity to immune cells within the device. The specification further notes that perforations within the container provide the means of "restrict[ing] the diffusion of these molecules from the device but permit[ing] the free ingress and egress of immune and other cells into and out of the device." *Id.* Further, the specification indicates that the "role of the perforations is to permit the entry of immune cells into the device which then come into contact with the antigen and co-stimulatory molecules to become primed, and then to permit egress of the primed cells. These objectives must be achieved while at the same time the perforated device must contain and maintain the desired levels of the antigen and co-stimulatory factors such as cytokines produced by the immune system cells within the device." Page 22, line 20 to Page 23, 3. Thus, the specification provides sufficient disclosure for the container having "means for limiting the passive diffusion of molecules out of said device without limiting the active movement of immune cells into or out of said device," and clearly indicates that perforations as well as the open ends of the container can provide the structure to accomplish this function.[1] *See* Page 22, line 17 to Page 23, line 7. *Ipsis verbis* support is not required.

In view of these remarks, Applicants respectfully submit that the rejection of claim 76 under 35 U.S.C. § 112, first paragraph, should be withdrawn.

[1] This limitation is consistent with a means plus function limitation under 35 U.S.C. § 112, ¶ 6.

CONCLUSIONS

Applicants respectfully request that the foregoing remarks be made of record in the file history of the instant application. Applicants submit that the remarks and amendments made herein now place the pending claims in condition for allowance. If a telephone discussion will help expedite processing of this application, the Examiner is invited to telephone the undersigned at (914) 762-7586.

Respectfully submitted,

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By: Frederick J. Hamble 42,623
Frederick J. Hamble (Reg. No.)

712 Kitchawan Road
Ossining, NY 10562
(914) 762-7586